



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 480-3387

March 16, 2021

Re: Animal Welfare Assurance  
#A3284-01 (OLAW Case 2J)

Dr. Jill Pipher  
Vice President for Research  
Brown University  
47 George Street -Box 1937  
Providence, Rhode Island 02912

Dear Dr. Pipher,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated March 11, 2021 reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Brown University. This animal activity is PHS-supported. According to the information provided, OLAW understands that on January 14, 2021, and again on February 5th, the IACUC identified several repeat deficiencies in the gnotobiotic mouse facility:

- Inconsistent or missing labeling on food, chemicals, waste, and autoclaved items;
- Lack of cleanliness in the animal use area;
- Inconsistent or missing logs;
- Presence of expired substances.
- Cages with soaked and soiled bedding; and
- Remnants of long-standing mouse remains within one cage.

Corrective and preventive actions included the following:

- The lab was placed on probation for six months with unannounced inspections in the form of post approval monitoring by the IACUC and the Center for Animal Resources and Education (CARE) staff.
- The PI must inspect the facility every week and report the findings of such inspections to the IACUC on a weekly basis.
- The lab must rectify all missing logs, labels, and information in the facility found during the latest round of semiannual inspections.
- The lab must update their current satellite facility SOP to clearly articulate the cage changing schedule and ensure consistency with what is written with the IACUC-approved animal use protocol.
- The lab may lose its privileges to maintain and operate the satellite gnotobiotic facility if continued deficiencies are identified.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident, provide corrective measures, and prevent recurrence. OLAW concurs that the incident warranted reporting. We are concerned that an animal carcass was found indicating that animal observations had not been done for some time. OLAW has found that this is often due to a lack of communication, or confusion, as to who is responsible for the animals. OLAW suggests that this responsibility be unambiguous and in writing. Another consideration may be to appoint a lab manager for research animal responsibilities. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

**Brent C. Morse -S**

Digitally signed by Brent C.  
Morse -S  
Date: 2021.03.16 10:17:20 -04'00'

Brent C. Morse, DVM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



# BROWN

March 11, 2021

Brent Morse, DVM  
 Director, Division of Compliance Oversight  
 Office of Laboratory Animal Welfare  
 National Institutes of Health  
 Rockledge 1, Suite 360  
 6705 Rockledge Drive  
 Bethesda, MD 20892

RE: Noncompliance Report, Assurance D16-00183 (A3284-01)  
 National Institute of Diabetes and Digestive Kidney Disease Award (DK113265)  
 National Institute of General Medical Sciences Award (GM109035)

Dear Dr. Morse:

The Brown University IACUC, through the Institutional Official (Jill C. Pipher, PhD), is writing to provide OLAW with a final report of the following repeat noncompliance with the *PHS Policy on Humane Care and Use of Laboratory Animals* ("PHS Policy"). Additionally, the IACUC deems this repeated noncompliance a violation of the housing standards described within the Guide for the Care and Use of Laboratory Animals and a violation of the IACUC's approved Satellite Facility Housing Policy and SOP.

On January 14, 2021, the IACUC performed a regularly scheduled semiannual inspection of the gnotobiotic mouse facility wherein several repeat deficiencies were identified:

- Inconsistent or missing labeling on food, chemicals, waste, and autoclaved items;
- Lack of cleanliness in the animal use area;
- Inconsistent or missing logs; and
- Presence of expired substances.

The lab was notified of the findings on January 20, 2021. A subsequent unannounced inspection on the morning of February 5, 2021 revealed that necessary corrective actions had not been taken and the following additional items were found:

- Cages with soaked and soiled bedding; and
- Remnants of long-standing mouse remains within one cage.

The IACUC discussed this issue of repeated facility deficiencies and noncompliance at its convened meeting on February 5, 2021, and determined the findings to be a repeat significant deficiency.

The following corrective actions were required effective February 8, 2021:

- The lab was placed on probation for six months with routine monitoring by the IACUC.
- The PI must inspect the facility every week and report the findings of such inspections to the IACUC on a weekly basis.
- The lab must rectify all missing logs, labels, and information in the facility found during the latest round of semiannual inspections.
- The lab must update their current satellite facility SOP to clearly articulate the cage changing schedule and ensure consistency with what is written with the IACUC-approved animal use protocol.
- The IACUC and the Center for Animal Resources and Education (CARE) staff will perform unannounced inspections in the form of post approval monitoring during this probationary period.
- The lab may lose its privileges to maintain and operate the satellite gnotobiotic facility if continued deficiencies are identified.

Brown University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. If you have any questions or concerns regarding this report, please contact [REDACTED] (b) (6)

Thank you for your consideration of this matter.

Sincerely,

[REDACTED] (b) (6)

Jill Pipher, PhD  
Vice President for Research, Institutional Official  
Brown University, Box 1937

cc: Diane Hoffman-Kim, PhD, IACUC Chair  
Lara Helwig, DVM, Attending Veterinarian  
[REDACTED] (b) (6)  
Keri Godin, Senior Director, Office of Research Integrity

## Wolff, Axel (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, March 12, 2021 7:19 AM  
**To:** IACUC  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Event Report - Assurance A328401

Thank you for this message, (b) (6) We will send a response shortly.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

**From:** (b) (6) On Behalf Of IACUC  
**Sent:** Thursday, March 11, 2021 3:45 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Diane Hoffman-Kim <Diane\_Hoffman-Kim@brown.edu>; Jill Pipher <jill\_pipher@brown.edu>; (b) (6)  
(b) (6) Keri Godin <keri\_godin@brown.edu>; Lara Helwig <lara\_helwig@brown.edu>  
**Subject:** Event Report - Assurance A328401

Dear Dr. Morse,

Please find attached the reportable event discussed by the IACUC during its convened meetings February 5, 2021 and March 5, 2021.

As a courtesy best practice, Brown University gives PIs a chance to review reporting letters prior to being sent. After the initial draft in February, the PI contested some of the points written within the letter. The committee evaluated those contested points during its convened meeting March 5, 2021 which is why the letter is going out now rather than in February.

Please let me know if you have any questions.

Sincerely,

(b) (6)

### Helpful Links:

- Brown IACUC website: <http://www.brown.edu/research/RPO/IACUC>
- InfoEd: [infoed.brown.edu](http://infoed.brown.edu)

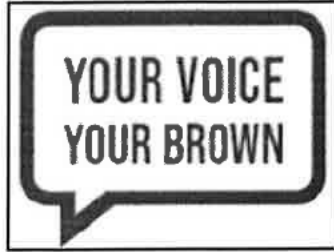
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